IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bauman et al.	)
		) Group Art Unit: 2615
Serial No.	10/773,731	)
		) Confirmation No. 8615
Filed:	February 5, 2004	)
		) Examiner:
For:	HEARING AID SYSTEM	) Walter F. Briney III
		)

SUBSTITUTE APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1) REAL PARTY IN INTEREST

The real party in interest is Vivatone Hearing Systems, LLC.

(2) RELATED APPEALS AND INTERFERENCES

Co-owned U.S. Patent Application Serial No. 10/325,529 has a co-pending appeal.

(3) STATUS OF CLAIMS

A Final Office Action issued on July 6, 2007 rejecting claims 1-12, 19, 21-24, 26-29, 35-38, 40 and 42-67. Claims 1-12, 19, 21-24, 26-29, 35-38, 40 and 42-67 are currently being appealed in the present application. Claims 13-18, 20, 25, 30-34, 39 and 41 stand as cancelled.

(4) STATUS OF AMENDMENTS

There are no after-final amendments.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The presently appealed claims describe an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal such that it provides an open ear configuration.

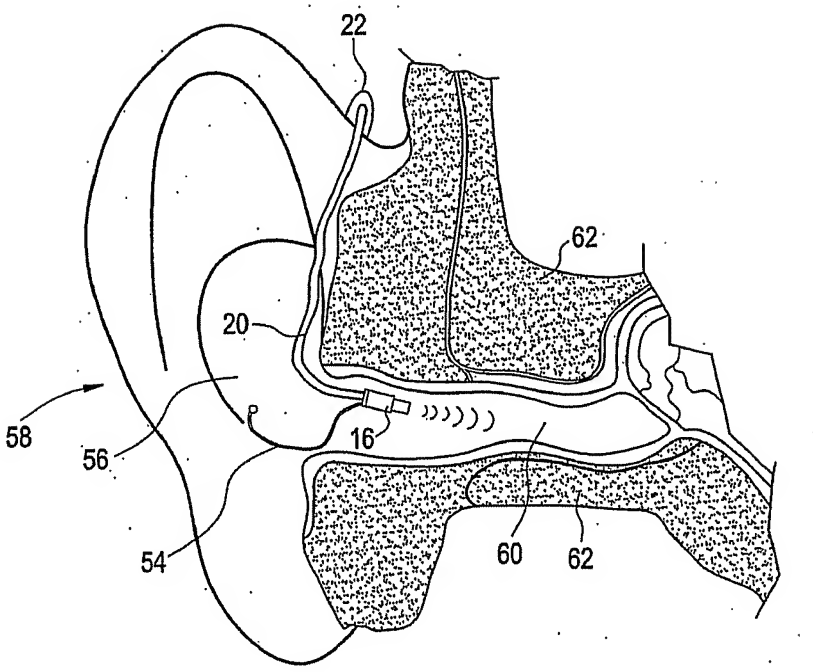
Both of the independent claims (1 and 36) require as shared limitations:

a microphone sampling position located externally of an ear canal of a user,

a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration,

wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

FIG. 5



With regard to the above, reference is made to the Applicant's FIGURE 5, which shows the receiver 16 suspended within the ear canal in an open ear configuration. A connector 22 of the behind the ear (BTE) unit 52 (see FIGURE 4) is illustrated above and behind the user's ear, with a connector 20 providing electrical connection between the BTE and the receiver. As is noted in paragraph 25, a microphone 27 is provided in or on the BTE. Also as noted in paragraph 33, the BTE includes a hearing aid amplifier and sound processing component 68.

In addition to the shared limitations described above, independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies. This is referenced at paragraph 8 and, with regard to the experimental data included within the specification, at paragraph 40.

In addition to the shared limitations described above, independent claim 36 further requires that the receiver have a maximum lateral dimension that is less than fifty percent of the maximum lateral dimension of a user's ear canal. Reference is made again to FIGURE 5, which

illustrates lateral dimensions of both the receiver 16 and the user's ear canal. Reference is also made to paragraph 31 and FIGURE 2, which describes exemplary relationships between lateral dimensions of the receiver 16 and of the ear canal.

(6) GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

Various legal errors of the Examiner will first be identified, followed by specific reference to the iterated rejections of the Examiner:

(A) The Examiner fails to give any weight to evidence of secondary considerations of non-obviousness;

(B) The Examiner claims that expert testimony itself is not valid evidence in support of non-obviousness, but must instead be supplemented by separate evidence;

(C) The Examiner improperly contends that motivation to modify references may be reasoned from alleged desires of "one of ordinary skill in the art" to avoid patent claim infringement (i.e., removal of a required claim component to avoid infringing the claim);

(D) The Examiner improperly contends that evidence of copying is not valid without providing evidence that, prior to copying, the competition conducted extensive research into finding their own solution;

(E) The Examiner did not recognize that the weight of the secondary consideration evidence obviated the proposed prima facie cases of obviousness;

(F) Claims 1-7, 40, 42-53 and 59-63 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,987,146 to Pluvinage et al. (hereinafter "Pluvinage");

(G) Claims 8, 26-29, 35-37 and 54-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the "Knowles product catalog";

(H) Claims 9 and 38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog and further in view of U.S. Patent No. 5,960,093 to Miller (hereinafter "Miller");

(I) Claims 64-67 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of U.S. Patent No. 4,425,481 to Mansgold et al. (hereinafter "Mansgold");

(J) Claim 1 has been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2004/0010181 to Feeley et al. (hereinafter "Feeley") in view of U.S. Patent Application Publication NO. 2003/0002700 to Fretz et al. (hereinafter "Fretz") and further in view of Pluvinage;

(K) Claims 19, 21-24 and 58 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of "GN Magazine from January 2005" in view of the "ReSound AiR pamphlet from September 2003" in view of the "GN ReSound article from April 2003"; and

(L) Claims 36-38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of the Knowles product catalog in view of Miller;

(M) Claims 10-12 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement;

(N) Claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

(O) Even assuming (simply for the sake of argument) that a viable prima facie case of obviousness has been made out, the claims are patentable by virtue of the overwhelming evidence of secondary considerations.

(7) ARGUMENT

(A) The Examiner fails to give any weight to evidence of secondary considerations.

The Applicants have submitted a large body of commercial success evidence to rebut any potential *prima facie* cases. As is noted in the Evidence Appendix, Vivatone President Leon Hirsch submitted numerous declarations detailing the commercial success of the Vivatone open ear hearing aid (which Vivatone enjoyed despite extremely minimal advertising), copying by numerous large competitors in the industry, laudatory statements by competitors that directly relate to the advantageous aspects of the Applicant's claimed open ear configuration, and the elimination of a long felt need in the industry by the introduction of Vivatone's open ear system.

During prosecution, the Examiner failed to give weight to the substantial body of submitted secondary consideration evidence. Though the Applicant argued this error, the Applicant further submitted declarations by field experts Drs. Glaser and Berlin as further support for the evidence of secondary consideration. However, the Examiner persisted in failing to give weight to the evidence of secondary consideration.

It is noted that the Board and the Examiner must consider and give weight to the secondary consideration evidence on record.

In *In Re John B. Sullivan, et al.* (August 29, 2007), the Federal Circuit vacated the Board's decision because it failed to give any weight to the rebuttal evidence of record. Most relevant to the resolution of the appeal, was the Board's statement in a footnote that:

> "The remainder of appellants [sic] arguments on this record, in addition to the Declarations of record, relate to the use of the claimed composition as an anti-venom. Since we have placed not [sic] weight on the intended use of appellants' composition we do not address these arguments or the Declarations."

The appellate court accepted that a *prima facie* case of obviousness had been set forth by the Examiner. However, with regard to the rebuttal evidence, the court noted that:

The Board stated in a footnote that the declarations of record relate only to the use of the claimed composition as an anti-venom, and thus the Board expressly declined to give any meaningful consideration to them. Sullivan, No. 2006-0220, slip op. at 13 n.7. As stated above, when an applicant puts forth relevant rebuttal evidence, as it did here, the Board must consider such evidence. The claimed composition cannot be held to have been obvious if competent evidence rebuts the prima facie case of obviousness. By failing to consider the submitted evidence, the Board thus committed error.

Moreover, the Board was mistaken to assert that the declarations only relate to the use of the claimed composition. The declarations do more than that; they purport to show an unexpected result from use of the claimed composition, how the prior art taught away from the composition, and how a long-felt need existed for a new anti-venom composition. While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence. Had the Board considered or reviewed the declarations in any meaningful way, it might have arrived at a different conclusion than it did.

Furthermore, the Board's focus on the intended use of the claimed composition misses the mark. The Board cites In re Zierden, 411 F.2d 1325 (CCPA 1969), for the proposition that a statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. In that case, applicant conceded that his composition was distinguished from the composition disclosed in a prior art patent only by the statement of intended use. Our predecessor court held that that intended use for the known composition could not render the claim patentable. In this case, applicant does not concede that the only distinguishing factor of its composition is the statement of intended use and, in fact, extensively argues that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. Such a use and unexpected property cannot be ignored. See In re Papesch, 315 F.2d 381, 391 (CCPA 1963)("From the standpoint of

patent law, a compound and all of its properties are inseparable; they are one and the same thing. . . . There is no basis in law for ignoring any property in making such a comparison."). The issue here is not whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use. That unexpected property is relevant, and thus the declarations describing it should have been considered by the Board.

As is noted above, the purpose of secondary consideration evidence is rebuttal of a prima facie case of obviousness, and the evidence must be properly considered (*See* Alco Standard Corp. v. Tennessee Valley Authority, 1 USPQ2d 1337, 1344 (Fed. Cir. 1986), *cert. denied*, 483 U.S. 1052 (1987) (While "standing alone, the prior art provides significant support for the ... contention that the ... patent would have been obvious," evidence of secondary considerations, including the solution of a long-felt need, served to "establish that [the] invention appearing to have been obvious in light of the prior art was not.").

(B) The Examiner erroneously asserts that expert testimony itself is not valid evidence in support of non-obviousness, but must instead be supplemented by separate evidence.

The Examiner's contends that the expert declarations do not constitute valid evidence in support of non-obviousness. This completely ignores the evidentiary nature of expert testimony. With specific regard to the Examiner's Action of July 6, 2007 beginning at page 20, the Examiner categorically discounts every point made by the audiology expert, Dr. Glaser. Exemplary quotes are extracted from the Examiner's July 6, 2007 action below:
at page 20, lines 9-10:

In paragraph 13, Dr. Glaser opens with the contention that Pluvinage requires sampling sound within the ear canal. This statement is made here without basis.

at page 20, lines 19-22:

In paragraph 14, Dr. Glaser reads Feeley as a teaching to occlude the ear canal despite the use of an "open mold."...This appears to be a non sequitur.

at page 21, lines 13-15:

Dr. Glaser refers to a loss of market share, yet this is undocumented and all discussion is, therefore, moot.

at page 21, lines 15-16:

Again, talk is made of penetration into the marketplace, but this has not been documented...

at page 21, lines 17-18:

Dr. Glaser notes that advertising hearing aids is expensive, but offers no evidence.

at page21, lines 18-21:

Dr. Glaser continues with a discussion of the Kirkwood reference, indicating that its market data is not germane to the Vivatone hearing aid since said hearing aid is not comparable. Again, this means no evidence concerning market success has been presented.

at page 22, lines 3-7:

Dr. Glaser finally concludes by stating "the Vivatone System is an advancement in that it rejects BTE-tube designs as well as the hybridized tube design of Pluvinage." ... there is no evidence of it rejecting the hybridized tube design of Pluvinage.

The Examiner's treatment of Dr. Glaser's testimony completely ignores the fact that each of Dr. Glaser's statements are themselves evidence. For example, Dr. Glaser, as one of ordinary skill in the art (reference is made to Dr. Glaser's substantial curriculum vitae, attached to Dr. Glaser's declaration), after review of the Pluvinage reference, testified that the Vivatone System rejects the hybridized tube design of Pluvinage. This testimony constitutes documentary evidence of that fact. The Examiner may not, in the face of that evidence, claim that there is no evidence of the Vivatone System rejecting the hybridized tube design of Pluvinage.

The Examiner similarly treated other points of Dr. Glaser's testimony, e.g., Dr. Glaser's characterization of the marketplace, his discussion of Vivatone's performance, including

penetration into the marketplace and market share, his technical understandings of the patent references, etc. The Examiner improperly ignored the evidentiary value of Dr. Glaser's expert testimony.

The Examiner similarly ignored the evidentiary value of Dr. Berlin's expert testimony, e.g.,:

at page 22, lines 15-17 (the Examiner discounts Dr. Berlin's technical understanding of the Pluvinage system and ignores his technical explanation):

> In paragraph 6, Dr. Berlin states that Pluvinage requires a sound sampling tube "to control feedback and make its own probe mike measurements." However, no evidence of this can be found in the reference.

at page 23, lines 12-17 (again, discounting Dr. Berlin's technical understanding of how the hearing aid system described by Pluvinage necessarily worked):

> In paragraph 8d, Dr. Berlin states that the wide-dynamic range compressor of Pluvinage could not operate without the second microphone tube: "the adaptations required of the processor were IMPOSSIBLE without the use and presence of the second sound tube." In essence, Dr. Berlin argues here that all ReSound hearing aids in the early 90s without the second sound tube of Pluvinage did not work. This is totally absurd.

at page 23, lines 20-21:

> In paragraph 9, Dr. Berlin argues just as Dr. Glaser does in paragraph 12 of his declaration. Ergo, this paragraph is unpersuasive for the same reasons.

at page 24, lines 1-4:

> In paragraph 10, Dr. Berlin states that Feeley requires a mold while Fretz describes a conventional BTE-tube design. From this, he concludes that the configurations would cause much more insertion loss than the Vivatone hearing aid. This is a very powerful charge to make, but again is without any evidence.

at page 24, lines 7-10:

In paragraph 11, Dr. Berlin argues that the Vivatone device claimed is not comparable to other devices in a market sense, that it was copied and lost market share, and spent little on advertising. These assertions were already treated supra regarding paragraph 16 of Dr. Glaser's declaration.

at page 24, lines 11-13:

In paragraph 12, Dr. Berlin cites advertising from the early 90's during the Gulf War; however, no evidence of the amount of money spent on and the success of such advertising is provided.

at page 24, lines 14-17:

In paragraph 13, Dr. Berlin states that Vivatone cannot be compared. Again, this means that no market data can be considered on the record, which renders any decision of market success a guessing game.

at page 25, lines 4-7:

Those sections of applicant's arguments that wholly depend on the declarations of Drs. Glaser and Berlin are not treated specifically below since the declarations have been found unpersuasive.

While we have reproduced a large number of the Examiner's categorical rebuttal of the expert declarations, we feel that it is illustrative of the Examiner's unwillingness to consider the evidentiary value of Drs. Glaser and Berlin's expert testimony. The evidentiary value of this expert testimony cannot be categorically dismissed.

(C) The Examiner improperly contends that motivation to modify references may be reasoned from alleged desires of "one of ordinary skill in the art" to avoid patent claim infringement (i.e., removal of a required claim component to avoid infringing the claim).

The Examiner contends that it is proper to find motivation to modify a patent reference by removing any limitation(s) that is recited in a claim. The Examiner's rationale is that "one of ordinary skill in the art" will want to remove that limitation (without reference to why the

reference teaches and claims the limitation) BECAUSE by doing so, the one of ordinary skill in the art will not infringe the claim. The Examiner's "rule" has a few fatal/unlawful flaws: 1) the rule would allow an Examiner to take any reference and apply (in a rejection) a new teaching that is an opposite of what is taught by the four corners of the document (e.g., if the patent document teaches building an automobile (claimed product) by providing, in part, an engine (limitation A), the Examiner would, by his rationale, have a viable document that also teaches an automobile without an engine); and 2) the rule would require that one of ordinary skill in the art be willing and able to legally review the claims to determine how not to infringe.

Indeed, the Examiner's assertions would mean that "one of ordinary skill in the art" would necessarily have to be a licensed patent attorney, having the training and ability to perform claim construction of claim terminology based on the specification and the prosecution history in order to understand whether a product that they might dispense would potentially infringe (assuming they even cared). To require "one of ordinary skill in the art" to be a patent lawyer goes completely against the plain language and purpose of looking to the understanding of "one of ***ordinary*** skill in the ***art***" when assessing motivation to combine references or otherwise modify a teaching. In this case, the "***art***" is Audiology, not patent law. Further "one of ***ordinary*** skill" in Audiology is not a patent lawyer turned Audiologist, or an Audiologist turned patent lawyer; it is an Audiologist.

(D) The Examiner improperly contends that evidence of copying is not valid without providing evidence that, prior to copying, the competition conducted extensive research into finding their own solution.

At page 25 of the Examiner's final action, lines 12-13, the Examiner indicates, "Absent the evidence of extensive research by competitors, the evidence is unpersuasive." The Examiner improperly indicated that in order to sustain any claim of copying by others in the industry (as evidence of secondary considerations), the Applicant must additionally submit evidence that the competition conducted extensive research into finding their own solution before copying the invention. **This is not true.**

As we noted in previous responses, this would be impossible, considering that competitors ***do not publish*** their internal research and development plans and results. ***Such a requirement would render the purpose of evidence of copying completely moot for purposes of***

examination in front of the Patent Office.

The Examiner may be referencing MPEP 716.06, which cites Dow Chemical without any comment:

> Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 837 F.2d 469, 2 USPQ2d 1350 (Fed. Cir. 1987). This cite comment is specific to Dow Chemical; it does not define a test for all evidence of copying.

Note the Decision before the Board of Appeals in *Ex parte DONALD G. GILLIS and DANIEL JOHNSON*, Appeal No. 2004-1753, Application No. 09/524,086, page 5, http://www.uspto.gov/go/dcom/bpai/decisions/fd041753.pdf. In that decision, the Board noted that the Examiner improperly failed to consider the evidence of secondary consideration. With regard to the evidence of copying, the board cited a declaration of inventor Gillis that illustrated that major suppliers in the industry copied the applicant's invention. ***The Board validated this evidence, but did not require evidence that those competitors conducted their own research and development prior to copying the applicant's invention.***

The Court in *Buildex Incorporated V. Kason Industries, Inc.*, also recognized that evidence of copying itself (without reference to failure of others) is viable in stating, "It is also significant that no one had designed a hinge like the 2850T for many years but that Kason introduced the 1263 shortly after the 2850T appeared." 665 F.Supp. 1021, 4 U.S.P.Q.2D 1803 (E.D. New York, 1987), citing *Allen Archery, Inc. v. Browning Manufacturing co.,* 819 F.2d 1087, 1092 (Fed.Cir.1987) (significance of copying); *Dow Chemical Co. v. American Cyanamid Co.,* 816 F.2d 617, 620 (Fed.Cir.1987) (same); *Akzo N.V. v. U.S. International Trade Commission,* 808 F.2d 1471, 1480 (Fed.Cir.1986) (same); *cf. Panduit Corp. v. Dennison Manufacturing Co.,* 810 F.2d 1561, 1571 (Fed.Cir.1987) (defendant copied inventions).

Similarly, the Court in *Vandenberg v. Dairy Equipment Co.* indicated that "the copying of an invention may constitute evidence that the invention is not an obvious one." 740 F.2d 1560,

1567 (Fed. Circ. 1984), citing Troy Co. v. Products Research Co., 339 F.2d 364, 367 (9th Cir. 1964), cert. Dismissed, 381 U.S. 930 (1965). The Vandenberg court further stated "this would be particularly true where the copyist had itself attempted for a substantial length of time to design a similar device, and had failed") *Id.*

Thus from the above, it is clear that evidence indicating failures of others to produce a solution is ***not essential*** to validate evidence of copying and ***does not de-facto detract*** from such evidence (either considering that a company's efforts would not be public or considering that such company did not, in fact, invent the product). Rather, it is merely supplemental to such evidence of copying. Proper consideration of the evidence of copying by the Board is respectfully requested.

(E) The Examiner did not recognize that the weight of the secondary consideration evidence obviated the proposed prima facie cases of obviousness.

In the December 18, 2006 office action, the Examiner laid out a lengthy rebuttal of all of the secondary consideration categories presented by the Applicant, including the evidence of commercial success, the evidence of copying by others, and the evidence of long felt need provided by the various declarations of Mr. Leon Hirsch (the contents of which are incorporated by reference).

Subsequent to the last office interview, we consulted the independent experts, Dr. Berlin and Dr. Glaser, in order to get an understanding of: 1) whether experts in Audiology would consider the Vivatone product to be successful; 2) whether experts in Audiology would consider Oticon, Hansaton, Interton, Siemens and Phonak to have copied Vivatone (rather than copying Feeley or Pluvinage designs); and 3) whether Vivatone really satisfied a long felt need in the industry (i.e., how did experts view the introduction of the Vivatone product (as just another product, or really a new category solving all sorts of needs in the art)). The declarations of Drs. Berlin and Glaser are also incorporated by reference.

Even a brief review of each of these experts Curriculum Vitae show that these two independent experts are in the top of their profession. Each of these experts comment both on the prior art rejections, and substantiate the viability of the secondary consideration evidence, including the evidence of commercial success, long felt need and copying.

As will be discussed in detail below, each independent expert wholly validated the

Vivatone product's commercial success; both refuted the Examiner's contention that Feeley or Pluvinage was copied (rather than Vivatone) and positively indicated that Vivatone was copied; and indicated that the Vivatone product was, indeed, a new category, revolutionary, etc., in the hearing aid industry.

The Evidence of Commercial Success

Both Dr. Berlin and Dr. Glaser positively declared that they considered the Vivatone hearing system commercially successful, despite minimal advertising, no name recognition, and market derived bars to entry (i.e., penetration of the market despite things like distributor loyalty to large manufacturers, large advertising campaigns by competitors, etc.).

The Vivatone Hearing Aid Was Revolutionary; A Head Turner

Referring to Dr. Glaser's Declaration, paragraph 16, Dr. Glaser positively indicates a belief that upon introduction, the marketplace regarded the Vivatone product as "a clever design that unequivocally turned heads in the Audiology community." Indeed, Dr. Glaser indicates that Vivatone "has done quite well in the marketplace because of their unique configuration and product presentation (the small BTE component with the microphone port, the thin speaker wire, and the small speaker suspended in the ear canal)." Thus, Dr. Glaser ties Vivatone's commercial success directly to key aspects of Vivatone's open design and positively indicates that the Audiology community saw the Vivatone hearing aid as "clever" and "a head turner."

We note that the Examiner expressed a belief that the Vivatone System was not the type of product that would be a head turner (the "I've got to have it" type of product similar to the Ipod). Dr. Glaser's declaration refutes the Examiner's claim. Dr. Berlin's declaration also directly refutes this in paragaph 13, indicating that the Audiology community could ***immediately see the unique value of the Vivatone system*** (the ability to emergently fit patients without resorting to molds, waiting or readjustment being just one of the advantages).

Dr. Berlin emphatically described the Vivatone product as "***revolutionary***", indicating that when he first saw the product in 2004, he felt that it would "***change the industry.***" (see paragraph 5 of the Berlin Declaration). Dr. Berlin also indicated that the Vivatone product would "***change the way hearing aids are made and distributed.***" (paragraph 11).

Vivatone's Commercial Success was Phenomenal; Sales Soared

Dr. Berlin also indicated that Vivatone's ***commercial success was "impressive,*** particularly because Vivatone spent very little on advertising and had no broad name recognition in the industry." He also indicated that "***most small companies fail for those same reasons.***" (See paragraph 11 of Dr. Berlin's declaration).

Dr. Glaser similarly declared that Vivatone's ***product sales "soared before similar competing products were introduced.***" Dr. Glaser noted that sales soared "***despite*** the fact that most Audiologists have *fairly strong ties to certain manufacturer's product lines* and ***despite*** the fact that Vivatone did *little direct advertising*" (citing *word of mouth industry buzz* /re Vivatone's product).

In sum, both experts cite substantial commercial success despite bars to market penetration for small companies (including little advertising, audiologist ties to existing manufacturer's product lines and lack of name recognition).

Advertising Directly Affects Sales

Both experts also discount the Examiner's contentions that the hearing aid industry is not affected by advertising (because advertising in the marketplace does not directly affect sales). Dr. Berlin ***directly refutes*** this statement in paragraph 12, citing Miracle Ear ads on CNN, and Beltone and Siemen's television advertising schemes. Referring to the Examiner's contentions, Dr. Berlin DIRECTLY states: "**Vivatone's commercial success was** driven by word-of-mouth referral and was **phenomenal** (despite minimal advertising). **It should not be discounted.**"

Dr. Glaser points to the need and activity of manufacturers in "*marketing their products to audiologists and hearing aid dispensers.*" (see paragraph 16). Dr. Glaser positively states, "**The hearing aid industry is heavily affected by advertising."** He continues, "**Marketing to professional audiologist as well as the consumers is an extremely expensive proposition within the hearing aid industry. As such, Vivatone's commercial success should be seen as even more remarkable because of the fact that Vivatone's advertising expenditures were so minimal.**"

The Examiner also quoted Alan Dozier from GN Resound, who stated "Not a lot of consumer advertising is being done to build confidence in hearing aid instruments and build

brand awareness." Dr. Glaser positively agrees with the statement as it relates to conventional hearing aids, but "***completely disagrees***" as it relates to Vivatone, which is a "***new category of hearing aids.***" (see paragraph 16 of Dr. Glaser's Declaration). Dr. Glaser further states that the Vivatone product "***has spurred a change in the hearing aid industry as it relates to marketing efforts. Indeed a great deal of advertising is now being done for this category (a 'this is not your father's hearing aid' type of response to the Vivatone configuration).***" Dr. Glaser cites the marketing materials of Oticon, Siemens, Hansaton, Interton and Phonak as exemplary.

Dr. Berlin similarly indicates that Alan Dozier's statement ***does not relate*** to "this new category of hearing aids." Dr. Berlin also cites the advertising of Oticon, Siemens, Hansaton, Interton and Phonak as ***directly reflective of industry change resultant from Vivatone's "revolutionary design."*** (see paragraph 14 of Dr. Berlin's Declaration).

The Revolutionary Nature of Vivatone Does Not Allow For Comparison With Conventional Designs (Re Market Data)

Related to Dr. Berlin's and Dr. Glaser's comments immediately above, the Experts do not consider Vivatone's market share to be comparable to other conventional categories of hearing aids, such as BTE-tube designs or BTE designs in general.

Dr. Glaser notes, near the end of paragraph 16, that "***comparison of the open canal Vivatone system*** (and the similar Oticon, Hansaton, Siemens, etc. systems) ***with conventional BTE tube systems*** is...not really effective (it is the ***'apples to oranges'*** comparison)." Dr. Glaser positively indicated that the Vivatone system was a "***new category of hearing aids.***" (see paragraph 16 of Dr. Glaser's Declaration).

Dr. Berlin similarly stated, "Vivatone is ***simply not comparable*** to other devices..." (paragraph 11). Dr. Berlin also stated, **"the revolutionary nature of the Vivatone system does not allow for comparison with conventional designs (even with "open fit" tube designs, which are a subcategory of the BTE category)."**

Accordingly, Vivatone held the entire market share of this new category, until Oticon, Hansaton, Siemens and others became competitors in this category by copying the Vivatone configuration. **The market data of other categories, even "open fit" tube designs, do not relate.**

In summary, the independent declarations of Drs. Berlin and Glaser can leave no doubt that the Audiology industry considers Vivatone to have enjoyed **phenomenal** and **un-refutable commercial success** by introducing Vivatone, **which the industry considered revolutionary/ the first in a new category of hearing aids/ a product that changed how the hearing aid industry manufactured, distributed and marketed hearing aids.**

The Evidence of Copying by Others

Drs. Berlin and Glaser Indicate Copying by Oticon, Siemens, etc. Rather than Feeley or Pluvinage

Dr. Berlin declared, at paragraph 5, that he considers Phonak, Siemens, Interton, Oticon and Hansaton to have copied Vivatone's essential configuration. Dr. Berlin does note that, "while various versions of these devices may have different or additional features, ***they have all taken Vivatone's essential design*** (***which design I considered and still consider to be revolutionary***), including the small BTE with the microphone port, the thin speaker connecting wire, and the small speaker suspended in the ear canal."

Dr. Glaser also declared, at paragraph 5, that "***since the introduction of the Vivatone hearing aid, other manufacturers have seen fit to produce hearing aids in this category.***" Dr. Glaser indicated (paragraph 9) that these competitors have taken the "principal element" of the Vivatone hearing aid design (despite having produced products with additional electronics, software compression, etc.). With regard to these copies of Vivatone, Dr. Glaser concludes, "...**the basis of their offerings in this new class of hearing aids obviously stems from the Vivatone product.**" In paragraph 16, Dr. Glaser states, "...**it is clear to me that the other major manufacturers of hearing instruments have seen fit to copy the product.**"

Drs. Berlin and Glaser made the above statements after being made aware of the Feeley and Pluvinage teachings. Despite those teachings, as evidenced by the above, they each independently and firmly believe that the essential Vivatone hearing aid system was copied rather than any of the teachings in the prior art. Dr. Berlin further indicates (paragraph 15) "...devices supposedly patented before Vivatone ***do not directly address*** the ***problems of Occlusion and Insertion loss*** separately ***in the creative manner exemplified by Vivatone.***" Dr. Glaser indicates at the end of paragraph 16, "**the Pluvinage instrument also does not compare. The Vivatone system is an advancement in that it rejects the BTE-tube designs as well as**

the hybridized tube design of Pluvinage."

Accordingly, the independent experts ***separately reject*** the Examiner's contention ***that the competitors copied the prior art*** Feeley or Pluvinage teachings, while at the same time ***separately confirm*** that these ***competitors copied the essential aspects of the Vivatone design.***

The Laudatory Statements of Competitors

The Examiner contended that the laudatory statements can be directed not only to the applicant's invention but to the Pluvinage and Feeley hearing aids. However, ***both Drs. Berlin and Glaser indicate the advertising of Oticon, Siemens, Hansaton, Interton and Phonak as directly reflective of industry change resultant from the introduction of the Vivatone product.*** (see Dr. Berlin's Declaration at paragraph 14 and Dr. Glaser's Declaration at paragraph 16). Further, each of the independent experts indicate that these competitors, while they may have varied features, such as additional electronics, software compression etc., ***obviously copied the essential or principal aspects of the Vivatone system (not the prior art).*** (See Dr. Berlin's Declaration at paragraph 5 and Dr. Glaser's Declaration at paragraph 9). **Accordingly, the laudatory comments relate directly to the essential aspects of the Vivatone device, and not the Feeley or Pluvinage devices.**

The Evidence of Long Felt Need

The Vivatone Hearing Aid Was Revolutionary

Referring to Dr. Glaser's Declaration, paragraph 16, Dr. Glaser positively indicates a belief that upon introduction, the marketplace regarded the Vivatone product as "a clever design that unequivocally turned heads in the Audiology community."

Dr. Berlin's, in paragraph 13, indicated that the Audiology community could ***immediately see the unique value of the Vivatone system*** (the ability to emergently fit patients without resorting to molds, waiting or readjustment being just one of the advantages). Dr. Berlin emphatically described the Vivatone product as "***revolutionary***", indicating that when he first saw the product in 2004, he felt that it would "***change the industry.***" (see paragraph 5 of the Berlin Declaration). Dr. Berlin also indicated that the Vivatone product would "***change the way hearing aids are made and distributed.***"

The revolutionary nature of the product is reflective of the fact that the Vivatone system

satisfied a long felt need. As noted by Dr. Berlin, the traditional, long felt problems of Occlusion and Insertion loss, have been obviated by Vivatone's non-obtunding design (paragraph 15).

Independently, Drs. Berlin and Glaser declared that the Audiology industry considers Vivatone's **commercial success to be phenomenal and un-refutable**. They indicated that **Vivatone pioneered a new, revolutionary category of hearing aids** that was **summarily copied by competitors because of Vivatone's unique essential configuration**. Drs. Berlin and Glaser confirmed that both the **copying and laudatory statements originate from Vivatone's unique essential configuration** and not the prior art. Drs. Berlin and Glaser also indicated that the genesis of this copying stems from the **Vivatone hearing aid's unique solution to the long felt problems** of the industry.

As is noted above, proper consideration of the above, substantial secondary consideration evidence must be made. This evidence provides textbook indicia of patentability.

(F) Claims 1-7, 40, 42-53 and 59-63 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage.

Of primary point, we note that Pluvinage does not teach the following limitation: "the receiver generating ***about three decibels or below of insertion loss*** over a portion of the human ear audible frequencies." The Examiner uses Pluvinage as its sole reference in this regard. More specifically, the Examiner asserts that the term "insertion gain," as used by Pluvinage in Figure 11 and Col. 8, lines 15-25, is the same thing as the insertion loss described and claimed by the Applicant. The Examiner also indicates that the claims are indefinite in this regard because of "things like non-linear varying unoccluded responses of ears and variability of stimulus."

As we have noted above, the presently claimed subject matter relates to insertion loss, not insertion gain. Reference is made to Dr. Berlin's declaration at paragraph 2(j), which teaches the differences between insertion loss and insertion gain. Insertion loss is a measurable value that does not vary according to SPL (this is because it is measured with the hearing instrument turned off). It is absolutely a measurement related solely to size of the hearing aid in the ear (no amplification function, no compression function). Accordingly, the claims are definite.

The Examiner also indicates that the "insertion loss" term is a mechanism of defining

structure according to function. This is not so. The Vivatone insertion loss is a characteristic of the open ear Vivatone system, which comprises a small speaker suspended in the ear and connected to the BTE via a thin wire.

With regard to the "about three decibels or below of insertion loss limitation", reference is made to Dr. Berlin's Declaration at paragraph 7 and Dr. Glaser's Declaration at paragraph 11. Therein, the independent experts clearly indicate that Pluvinage does not teach about three dB or below of insertion loss. Pluvinage's teachings about insertion gain ***can have no bearing*** on insertion loss. At paragraph 6, Dr. Berlin indicates that the described Pluvinage system, which requires multiple tubes/components side by side in the ear canal, significantly occludes the ear canal relative to the Vivatone configuration (indeed, because of this significant occlusion, it would make sense that this system would generate significant insertion loss).

Dr. Glaser similarly indicates, at paragraph 11, that Pluvinage does not teach three decibels or below of insertion loss or that, in a switched off mode, the side-by-side profile would generate three decibels or below of insertion loss.[1]

Because the three decibel or below of insertion loss limitation is not taught or suggested by Pluvinage, a prima facie case of obviousness has not been made out. Thus, the Examiner's rejections are in error.

Further, as noted by Dr. Berlin's declaration, paragraph 6, removal of the sound sampling tube was not an obvious change at the time of the Pluvinage application. Specifically, Pluvinage **REQUIRED** the microphone tube or microphone in the ear canal *to control feedback and to make its own probe microphone measurements*. Because the proposed modification is improper, the Examiner's rejections are similarly in error.

Dr. Glaser also noted, at paragraph 13 of his declaration, that an audiologist possessing ordinary skill in the art would not have been motivated to modify the Pluvinage device to achieve the Vivatone hearing aid system. Dr. Glaser also notes that Pluvinage ***requires*** *both delivery of and sampling of sound within the ear canal.*

Because the requisite motivation to modify the Pluvinage device is lacking, as independently confirmed by two experts in the field, the Examiner's rejections are in error.

---

[1] Dr. Glaser also indicates (even though Pluvinage's measured insertion gain has no bearing on its insertion loss) that even at 80 dB SPL, for certain frequency ranges, Pluvinage's insertion gain is shown to be greater than 3dB in Figure 11.

The foregoing also makes sense with regard to Pluvinage's best mode requirement. Pluvinage believes that its multi-component configuration is ideal. Indeed, as noted by Dr. Berlin, Pluvinage ***requires*** the microphone tube or microphone in the ear canal *to control feedback and to make its own probe microphone measurements.* Pluvinage clearly disclosed its best mode, ***which requires the microphone tube or microphone in the ear canal*** (indeed, Pluvinage was obligated to).

Pluvinage did not disclose the Vivatone system (if Pluvinage believed such a system was better, it would have and should have disclosed it). Because Pluvinage **REQUIRES** the microphone tube or microphone in the ear canal, and/or because there is no motivation within Pluvinage to remove the sound tube to essentially find the Vivatone system (the prohibition against hindsight reconstruction and using the Applicant's own specification as a roadmap is reiterated), the rejection is improper.

In sum, the Pluvinage system 1) does not teach or suggest the "three decibels or below of insertion loss" limitation; 2) would not work as intended should the microphone tube be removed; and 3) does not provide motivation to make such a change. Further, Dr. Berlin and Dr. Glaser each noted Pluvinage's ***requirement*** for the sound tube ***and the lack of motivation*** within Pluvinage or within the art to remove that sound tube.

As to the Examiner's assertion that one skilled in the art would be motivated to remove the sound tube ***to avoid infringing the Pluvinage claims***, both Dr. Berlin and Dr. Glaser noted that they would ABSOLUTELY not have known to do this, since they are not patent lawyers. They would not have even been thinking along those lines.

Indeed, as is noted above, the Examiner's assertions would mean that "one of ordinary skill in the art" would necessarily have to be a licensed patent attorney, having the training and ability to perform claim construction of claim terminology based on the specification and the prosecution history in order to understand whether a product that they might dispense would potentially infringe (assuming they even cared). To require "one of ordinary skill in the art" to be a patent lawyer goes completely against the plain language and purpose of looking to the understanding of "one of ***ordinary*** skill in the ***art***" when assessing motivation to combine

references or otherwise modify a teaching. In this case, the "***art***" is Audiology, not patent law. Further "one of ***ordinary*** skill" in Audiology is not a patent lawyer turned Audiologist, or an Audiologist turned patent lawyer; it is an Audiologist. The Examiner's rejections are in error.

Reference is made to portions of Dr. Berlin's declaration ***refuting*** the Examiner's contentions that: 1) there is motivation to remove the microphone sampling tube of Pluvinage; and 2) that Pluvinage would work just as well without the microphone sampling tube. The below details the expert testimony that independently confirms how the Examiner's rejections are in error.

In relevant part, Dr. Berlin identified exactly how the microphone sampling tube is **ESSENTIAL** to Pluvinage. In paragraph 8(a), Dr. Berlin indicates that "***BOTH tubes are required, one to record ambient sound through the resonance peaks of the ear canal and the other to bring sound from the processor (described later as a multiband compressor...) to the speaker or receiver in the ear canal.***"

In paragraph 8(b), Dr. Berlin notes that the purpose of the second tube was ***essential*** to the device's multipurposes...***to use the ear's natural resonances*** to shape and color the incoming speech, to use the ***microphone in the ear to sense and correct for feedback,*** (section 8 lines 27-39 and elsewhere)...and to ***receive and compare a plurality of signals*** (Column 7 Lines 6-16). All of this speaks to and refutes the Examiner's contention that the second microphone and/or tube could be removed with no real changes to the device. ***In light of Dr. Berlin's rebuttals, the Examiner's contention is clearly not supportable.*** Accordingly, the rejections based on Pluvinage are in error.

Dr. Berlin goes on to indicate in paragraph 8(c) that in their discussions, the Examiner discounted the contents of the processor as being "unknown". However, Dr. Berlin noted that it actually was clearly described in the text as a ***Wide-dynamic range compressor*** (See Columns 6 lines 48 to 67: Column 7 lines 6 –16), which he recognized to be a ReSound ™ hearing aid, ubiquitous in the early 90s as the best device available for ordinary sensori-neural loss.

Dr. Berlin notes: "***The adaptations required of the processor were IMPOSSIBLE without the use and presence of the second sound tube. This sound tubes creates a servo-system connecting microphone to processor to speaker or receiver and smoothing and/or feedback reducing the entire frequency response.***"

This servo-system is a required aspect of the hearing aid system taught by Pluvinage. The Examiner contends that Dr. Berlin is asserting that all ReSound hearing aids from the 90s would require this servo-system. Dr. Berlin is not indicating this. Rather, he indicates that the system taught by Pluvinage relies upon and requires this servo-system, of which the sound tube within the ear canal forms an integral part.

In paragraph 8(e), Dr. Berlin unequivocally states, **"In summary, the device would not work as intended without the second tube."**

Keeping all of Dr. Berlin's statements in mind, it is clear that, not only would one of ordinary skill in the art **NOT be motivated** to remove the microphone sound tube, the described hearing aid is **REQUIRES** the microphone sound tube. Thus, there can be no motivation to modify Pluvinage. It is also by virtue of this that *KSR International Co. v. Teleflex Inc. et al.* does not apply. There can be no motivation to remove the sound tube when the teachings require the sound tube. Additionally, a *prima facie* case is not made out because the "3dB or below of insertion loss" limitation is not taught by Pluvinage.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As noted by Dr. Berlin, there is no motivation in Pluvinage to remove the sound tube (By direct contrast, the sound tube is ESSENTIAL). Accordingly, the testimony of Dr. Berlin confirms that the Examiner's rejections are in error.

Dr. Berlin also noted that the hearing aid ***would not work as intended*** without the second tube. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). As indicated by Dr. Berlin, removal of the microphone sound sampling tube would render the device unsatisfactory for its intended purpose and/or change the principle of operation of the device. **This is a direct indication that there can be no motivation to modify Pluvinage.** As above, Dr. Berlin confirms that the Examiner's rejections are in error.

The Examiner also noted a belief that removal of the sound tube would be inherent in light of the Pluvinage reference. However, we have noted Dr. Berlin's comments indicating how the microphone sound tube is ESSENTIAL to the Pluvinage hearing aid. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Because the sound tube is ESSENTIAL to Pluvinage, the lack of that sound tube ***cannot "necessarily flow"*** from the teachings of Pluvinage.

(G) Claims 8, 26-29, 35-37 and 54-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the "Knowles product catalog."

Claims 8, 26-29, 35-37 and 54-57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog. Specifically, the Examiner notes the EH series receiver with a dimension of 3.55mm, which the Examiner indicates is less than half of the average opening of the ear canal at 10mm. However, this rejection ignores that the Pluvinage system includes not just a receiver, but also a microphone or microphone tube alongside the receiver (which would also likely include a casing around the bare receiver). Ignoring the probable casing, just the receiver and adjacent microphone or microphone tube would provide for a maximum lateral dimension that would exceed 50% of a user's ear canal lateral dimension. (See the Declaration of Dr. Berlin at paragraph 7 and the Declaration of Dr. Glaser at paragraph 12). These rejections are similarly in error.

(H) Claims 9 and 38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog and further in view of Miller.

Miller teaches a receiver, which as is noted at Column 2, lines 28-30, is particularly suited for in the canal (ITC) hearing aids, which include the receiver, microphone and amplifier in a mold within the canal. There is no motivation within Miller to suspend this receiver in an open ear configuration within the ear canal, such as is claimed by the Applicants.

The deficiencies of Pluvinage have already been detailed above. This rejection also ignores that the Pluvinage system includes not just a receiver, but also a microphone or microphone tube alongside the receiver (which would also likely include a casing around the

bare receiver). Ignoring the probable casing, just the receiver and adjacent microphone or microphone tube would provide for a maximum lateral dimension that would exceed 30%, or indeed, 50% of a user's ear canal lateral dimension. (See the Declaration of Dr. Berlin at paragraph 7 and the Declaration of Dr. Glaser at paragraph 12). These rejections are similarly in error.

(I) Claims 64-67 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of Mansgold.

While Mansgold does teach multiple sound programs within a hearing aid, Mansgold does not make up for the deficiencies of Pluvinage, as are detailed above. Because of this, the rejections are similarly in error.

(J) Claim 1 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz and further in view of Pluvinage.

Essentially, the Examiner indicates (reference is made to the Examiner's descriptions of the deficiencies of Feeley at page 14, lines 8-11 of the Examiner's July 6, 2007 action) that Feeley does not teach the Applicant's invention because: 1) Feeley requires a mold; and 2) Feeley does not teach the "three decibel or below of insertion loss" limitation of claim 1. The Examiner then indicates that Fretz teaches that blocking of the ear canal can be undesirable, and that venting of molds may not be sufficient.

The Examiner then makes a mental leap by saying that, based on the teachings of Fretz, it would be obvious to do away with the Feeley mold and suspend a speaker in the ear canal. ***However, Fretz did not teach this.*** Fretz's alternative to molds was to route a ***sound tube*** from a BTE into the ear canal. Sound tube BTEs are known.

Feeley's design is from a different class (BTE plus mold). Feeley taught that the mold should preferably be inserted deep within the ear canal such that it touches the bony portion of the ear canal (thus avoiding the occlusion effect). While Feeley does teach that venting may be used, it does not indicate that removal of the mold would be beneficial or desirable (indeed, Feeley requires the mold).

*Feeley does **not** indicate or suggest a solution better than a deeply inserted mold in the ear canal (vented or not). Fretz does **not** indicate or suggest a solution better than routing a*

sound tube from a BTE into the ear canal. There is no motivation to combine these references. It is also by virtue of this that *KSR International Co. v. Teleflex Inc. et al.* does not apply. There can be no motivation to remove the mold of Feeley when the teachings require the mold. Additionally, as is noted above, a *prima facie* case is not made out because the "3dB or below of insertion loss" limitation is not taught by Feeley or Pluvinage.

The Examiner also indicates that the Feeley receiver may be replaced with "any Knowles receiver", as per teachings in Pluvinage. Even if this were the case, it would still be a Knowles receiver secured within a mold (since Feeley requires a mold).

All of the above is reinforced by the declarations of both independent experts, Dr. Berlin and Dr. Glaser. Each indicates that the proposed modification is unsupported by motivation from the references and the art.

Specifically, Dr. Glaser notes, at paragraph 14, that the Vivatone system is **not** an obvious modification of the Feeley System nor the system described by Fretz.

Dr. Berlin similarly indicates, at paragraph 8, that Feeley and Fretz are disparate solutions, and that one of ordinary skill in Audiology would **not** be motivated to change the CIC device of Feeley. As stated by Dr. Berlin, "Feeley does not describe suspending a speaker in the open ear in any way, the ear canal is not open, and the term 'open mold' merely describes a mold vent." Feeley is not, "and does not suggest the essential Vivatone configuration."

In sum, both independent experts positively declared that one of ordinary skill in the art would not be motivated to modify Feeley with the teachings of Fretz (The Figure 11 "insertion gain" teachings of Pluvinage having been addressed above, which is incorporated by reference) to result in the Vivatone configuration. The art does not in the least teach or suggest suspending the receiver of Feeley in any way for an open ear receiver fit. The Examiner's rejections are in error.

(K) Claims 19, 21-24 and 58 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of "GN Magazine from January 2005" in view of the "ReSound AiR pamphlet from September 2003" in view of the "GN ReSound article from April 2003."

The ReSound AiR pamphlet does teach a plastic "sport lock" for the traditional BTE sound tube type hearing aid. It does not teach such a retaining member extending from an

electrical connector or a receiver in the ear canal. The Examiner acknowledges that neither Feeley nor Fretz teach such a retaining member. As is noted above, Fretz is simply a BTE-sound tube hearing aid. Feeley has no need for such a retaining member because it is a mold, and because it is preferably inserted deep into the ear canal such that it contacts the bony portion of the ear canal. Given the disparate natures of these devices (i.e., mold of Feeley contacting the canal and the BTE-sound tube natures of Fretz and ReSound AiR), there is no motivation to make these changes. The Examiner's rejections are in error.

(L) Claims 36-38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of the Knowles product catalog in view of Miller.

As is noted above, regardless of the receiver chosen for Feeley, the result is still another receiver provided in an ear canal mold. The lateral dimension aspects of the claims (which relate to the profile of the claimed receiver suspended in an open ear configuration) are still not met. The Examiner's rejections are in error.

(M) Claims 10-12 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner rejected claims 10-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner indicates a belief that small receivers could not have been made at the priority date of the present application. As evidence of this, the Examiner cites the Knowles FK series receiver, which has a rectangular cross section with a maximum dimension of 2.73mm (the Examiner indicates a belief that the receiver must be 2.0mm to be enabled). The Examiner relies upon the FK receiver's 1999 manufacture date and believes that because he has not heard of a smaller receiver since then, that such receiver cannot be produced. This ignores the fact that such a receiver could be made, e.g., with a round cross section (the commercial Vivatone has a roughly round cross section). The Examiner's rejections are in error.

(N) Claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

The Examiner initially indicates that claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 are indefinite with regard to the hearing aid receiver generating about three decibels or below of insertion loss. The Examiner specifically believes that the insertion loss is relative to sound input levels (thus providing non-linear amplification or attenuation of sounds, etc.). As has been noted above, insertion loss is measured with the hearing aid turned off (note, the Examiner is again confusing this with "insertion gain" as described by Pluvinage, Figure 11). Since the hearing aid is turned off, it stands to reason that there is no need for an indication of sound input levels. This rejection is in error.

Indeed, during the last interview with the Examiner, this term was differentiated from the term "insertion gain." The Examiner suggested amendment of paragraph [0037] to specify that the insertion loss, or insertion effect, is the difference between Real Ear Unoccluded Response and Real Ear Occluded Response. The Examiner also suggested that the inventor, Dr. Bauman, provide a declaration indicating that the specification and the claims relate to insertion loss, as distinguished from insertion gain.

We previously understood that this issue was resolved. Nevertheless, because the Examiner has reiterated this rejection in the final action, we will detail how the specification relates to insertion loss rather than insertion gain:

In the December 18 office action, the Examiner attempted to equate the "insertion loss" as described and claimed by the Applicant with the "insertion gain" described by U.S. Patent No. 5,987,146 to Pluvinage (hereinafter "Pluvinage"), and in particular the insertion gain described by Figure 11.

During the last office action, the Examiner conceded that: 1) the Applicant described and claimed "insertion loss"; and 2) that Pluvinage described "insertion gain." The Examiner also recognized that insertion loss is always measured with the hearing instrument turned off, whereas insertion gain is always measured with the hearing aid turned on. The Examiner did contend, however, that insertion loss and insertion gain could be equated at high sound pressure levels (SPLs). We disagree; and more importantly, the independent experts disagree.

Reference is made to the Declaration of Dr. Charles Berlin, paragraph 2, for a description of "insertion loss", "insertion gain", and the incompatibilities of those distinctly different measurement types. Reference is also made to the Declaration of Dr. Glaser, paragraph 10, for a similar description of insertion loss.

In paragraph 2, (b) and (c), Dr. Berlin first notes how Real Ear Unaided Response (REUR) measurements are performed. This measurement forms the baseline for either "insertion loss" or "insertion gain" measurements.

In paragraph 2, (d), Dr. Berlin indicates that insertion loss is measured with the hearing aid turned off, wherein the absolute value of the difference of the sound measured with the hearing aid in place and the REUR is the insertion loss.[2]

In paragraph 2, (j), Dr. Berlin indicates that insertion gain must be measured with the hearing aid turned on. Dr. Berlin also indicates that insertion gain and insertion loss cannot be considered the same thing (Insertion gain can drop to zero if the amplifier is exerting a compression function, but this does not equate to zero insertion loss).

Insertion gain is an amplification/compression function that bypasses any obstruction in the ear canal caused by the hearing aid. If one were to place a speaker inside a room and feed a microphone source from outside the room, measurement of the sound from that speaker has no bearing on how thick or acoustically transparent the door is. That is, a hearing aid may have zero or near zero insertion gain by virtue of a compression function, but still have substantial insertion loss by virtue of its size in the ear canal. Pluvinage does not teach three decibels or below of insertion loss.

Dr. Glaser also indicates that insertion loss and insertion gain, as used by Pluvinage, are not comparable (see paragraph 11 of Dr. Glaser's declaration).

In sum, the Applicant describes and claims insertion loss and not insertion gain. Further, because of the nature of the two terms, insertion loss and insertion gain are not comparable (this has further relevance with regard to the Pluvinage rejections, discussed below).

The Examiner also indicates that claims 8-12, 36-38, 56, 57, 61, 63, 65 and 67 are all indefinite in that they recite that a maximum lateral dimension of the receiver is less than a certain percent of the maximum lateral dimension of a user's ear canal. However, simply because the maximum lateral dimensions of users ear canals vary does not render the claim indefinite. On a per user basis, such measurement may be readily made. Further, as the

[2] As a sidebar, it is also noted that Dr. Berlin indicates that open or vented molds (as in Feeley) present measurable insertion losses, whereas the Vivatone device presents almost no insertion losses (See paragraph 2, (g) and (i)).

Examiner attempts to do, such dimensions (more practically) may be based on averages of users (there is a fairly defined range of ear canal dimensions).

(O) Even assuming (simply for the sake of argument) that a viable prima facie case of obviousness has been made out, the claims are patentable by virtue of the overwhelming evidence of secondary considerations.

It should be emphasized that the Applicant has pursued two separate lines of arguments with regard to the Examiner's rejections:

(A) The Examiner's attempted prima facie case of obviousness has numerous flaws, as is evident from a review of the above. For example, we have pointed out that Pluvinage completely fails to teach the 3 dB or below insertion loss limitation. We have also described how the dual tube design of Pluvinage is specifically designed to provide a servo-system connecting microphone to processor to speaker or receiver and smoothing and/or feedback reducing the entire frequency response. We have also explained how the requirement for a mold in Feeley renders it incompatible with Fretz, which is a conventional BTE-sound tube device. Due to the evident flaws in the Examiner's attempted prima facie case, the claims should be judged patentable on the merits.

(B) However, even assuming (simply for the sake of argument) that the Examiner put forth a viable prima facie case of obviousness, we have submitted an expansive body of evidence including secondary considerations that are overwhelmingly in support of patentability of the claims.

A. THE FIRST DECLARATION OF LEON HIRSCH

On September 14, 2006, we submitted the declaration of Mr. Leon Hirsch, president of Vivatone Hearing Systems. This declaration provided evidence of commercial success; evidence of copying by competitors; evidence of long felt need in the industry; and evidence comprising laudatory statements by competitors.

WITH REGARD TO THE COMMERCIAL SUCCESS EVIDENCE

As was discussed in the declaration, when the open ear hearing aid system described and claimed was first commercially launched by Vivatone in the first quarter of 2004, Vivatone was a small startup company whose product line consisted solely of the open ear hearing aid product. Vivatone did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivatone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were $1,500 in 2004 and $16,000 in 2005, which amount is extremely minimal.

Notwithstanding the lack of name recognition and advertising, Vivatone's open ear hearing aid has achieved a high degree of commercial success. Indeed, as may be seen from the sales charts at Exhibit 2 in the declaration, domestic unit sales and domestic net revenues steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were $27,000 in the first quarter of 2004, $3,420,000 for the full year of 2004, and more than quadruple that in 2005 to $14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivatone's open ear hearing aid went from no sales to almost eighteen million dollars. Again, those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.

WITH REGARD TO LONG FELT NEED IN THE INDUSTRY

The Declaration of Leon Hirsch also details how, despite the fact that BTE, CIC, ITE and ITC hearing aids have been available for decades, it was only between 2002 and 2004 (that is, between Vivatone's application for patent and introduction of a commercial open ear hearing aid system) with the introduction of the Vivatone's hearing aid system, that a truly open ear hearing aid system shedding all of the disadvantages of the BTE, CIC, ITE and ITC devices was introduced to the industry. Thus, it took decades for the hearing aid industry to create Vivatone's novel open ear hearing aid system innovation.

While the open ear hearing aid system described by Vivatone's claims took decades to create, it is significant that the above types of hearing aids, and indeed, vented CIC units per se, have been known. Thus, despite the fact that vented CIC units were known, no other company in the field of hearing aids were motivated to separate the electronics from the speaker in the ear canal and place the electronics in a behind the ear unit, electrically connected to the open ear

receiver, until Vivatone did so. It is reasonable to conclude that on this evidence alone, (that is, the fact that it took many years for a company to incorporate provide such an arrangement as did Vivatone despite the fact that vented CIC units were well known), it would not have been obvious to provide a hearing aid device with behind the ear electronics connected to an open ear receiver suspended within the ear canal or to modify the teachings the cited art to provide for such open ear configuration.

WITH REGARD TO THE EVIDENCE OF COPYING AND LAUDATORY STATEMENTS MADE BY COMPETITORS IN THEIR ADVERTISING

We also noted in the declaration that, since the release of Vivatone's commercial product, there has been ***substantial copying*** of Vivatone's open ear configuration by the large, well-known hearing aid companies. Also, these large and well known companies have been ***aggressively marketing*** (i.e., numerous and overtly pointed comments relating to) ***the open ear aspects, which have been copied*** from the Vivatone device and that are described in the pending independent claims.

For example, in February, 2006, approximately 25 months after the introduction of the Vivatone's open ear hearing aid system (note that while Vivatone's sales were $27,000 in the first quarter, over the course of two years, sales amounted to almost eighteen million dollars), a direct competitor of Vivatone introduced the Oticon "Delta" hearing aid, (hereafter referred to as the "Oticon Delta")(See the Oticon stock exchange announcement at Exhibit 3, dated February 1, 2006). Oticon is a large, famous and internationally well known hearing aid manufacturer doing over five hundred million dollars ($500,000,000) a year generally in hearing aid sales. As described below, the Oticon Delta includes Vivatone's open ear hearing aid invention. Also, the Oticon marketing literature related to the Oticon Delta continually highlights aspects of Vivatone's open ear hearing aid invention as an extremely significant advance in the hearing aid field. More than that, Oticon uses it's marketing literature in conjunction with it's well known name in the hearing aid industry and, despite Vivatone's prior sales, claims to be the "first hearing aid device in a new category – RITE" (or Receiver in the Ear") (See Declaration of Leon Hirsch, Oticon Delta web page captures at Exhibit 4).

Exhibits 3 – 6 from the Declaration of Leon Hirsch provide various announcements, web page captures and product brochures from the Oticon web site, which describe the Oticon Delta

hearing aid as newly providing the hearing aid industry with the next generation of communications solutions in the RITE (Receiver In The Ear) category. The February 1, 2006 Oticon's stock exchange announcement (Exhibit 3) describes the Oticon Delta as consisting "of two units connected by an ultra-thin, almost invisible copper wire." The announcement goes on to state, "This copper wire connects a newly developed speaker placed inside the ear canal with a small, triangular, digital amplifier placed discretely behind the ear." Oticon's announcement also practically mirror's the present application's specification language as well as Vivatone's brochure language when it states, "By moving the electronics parts behind the ear, we have made room for a completely open solution, without compromising the cosmetic and audiological advantages of the in-the-ear hearing aids." As is clear, for example from Exhibit 3, the Oticon Delta is the same open ear hearing aid system as is embodied by the Vivatone open ear hearing aid system, for which a patent was presently applied for more than 35 months prior to the announcement of the Oticon Delta and for which the Vivatone product was commercially available more than 25 months prior to the announcement of Oticon Delta. This is ***clear evidence of copying*** in the industry, and as will be described below, ***clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace.***

Specifically referencing the presently pending independent claim 1, which is reproduced in relevant part above, ***the marketing literature for Oticon Delta exactly embodies the bulk of the limitations within the claim. Also, our tests of the Oticon Delta have further shown that the Delta meets the limitation requiring about three decibels or below of insertion loss over a portion of human audible frequencies.***

Referring specifically to the Oticon brochure entitled "Delta's Audiology Concept", Exhibit 5, Oticon states, "With Delta's innovative design, we were able to place the microphones and battery behind the ear in an extremely discrete shell-set and place the Receiver In The Ear (RITE)." Referring specifically to the Oticon Delta design description on Oticon's website, Exhibit 6, the behind the ear unit (1) includes the digital amplifier and microphone sampling ports. The BTE unit connects to the speaker (3), which is in the ear canal, via a thin sound wire (2). The receiver (3) is suspended in the ear canal with their open dome, which includes three arms extending radially away from the speaker toward the ear canal walls (as noted in the Delta Audiology Concept brochure, Exhibit 5, the "open dome used in Delta provides for the same acoustic response as an open ear, thus providing total occlusion relief.") (note also that the same

brochure contrasts the open ear configuration with use of vents in CIC (completely in canal) hearing aids by noting, "...even with a collection vent, the deep insertion of a CIC does not allow for a totally occlusion free fitting...the resulting occlusion is often enough to limit the acceptance of traditional technology for this very particular group.") ***Based on the foregoing, all of the elements in the independent claims of the above-referenced application are copied by the Oticon Delta device and are lauded by the Oticon Delta marketing literature.*** Since the Vivatone hearing aid was launched in the commercial market more than 2 years prior to the launch of the Oticon Delta, ***it is evident that Oticon Delta copied Vivatone's open ear hearing aid system innovation.***

Further, it is significant that ***each and every*** mention of the new Oticon Delta includes laudatory statements regarding the benefits of the open ear configuration (that is, a BTE combined with an open ear RITE) thus supporting the nonobviousness of the presently pending claims.

Reference is made to the Declaration of Leon Hirsch, which itemizes just some of Oticon's numerous laudatory remarks relative to the benefits of the open ear system, including separating the amplifier from the speaker, positioning of the BTE relative to the open ear receiver and using a thin wire to connect the two.

Though it will not be exhaustively reproduced here, the September 14, 2006 Declaration of Leon Hirsch also details how another large competitor, Hansaton, copies and extols the virtues of the claimed open ear hearing aid system.

B. THE SECOND DECLARATION OF LEON HIRSCH

On November 2, 2006, Leon Hirsch provided a second Declaration. This declaration provided evidence that Siemens, which until recently was the largest hearing aid manufacturer in the world (and is now believed to be the second largest), announced the Centra Active, which is what they call a RIC ("Receiver in the Canal") product.

On October 17, 2006, Siemens Audiologische Technik, GmbH ("Siemens") announced its own RIC ("Receiver in the Canal") hearing aid, called the "CENTRA Active", which is to be released in the beginning of 2007. *See* the Seimens press release at Exhibit 1, attached hereto. Seimens is also a direct competitor of Vivatone and is currently at least the second largest

hearing aid manufacturer in the world (our understanding was that until recently, Siemens was the largest). The Declaration also details how the CENTRA Active also copies Vivatone's open ear hearing aid invention, as well as how and where the Siemens marketing literature related to the CENTRA Active continually and openly highlights Vivatone's open ear hearing aid invention as a significant advance in the hearing aid field.

C. THE THIRD DECLARATION OF LEON HIRSCH

On November 28, 2006, we submitted a third Declaration from Leon Hirsch, which declaration detailed how a fourth large competitor, Interton Horgerate, GmbH, introduced a new "Receiver in the Ear" (RITE) hearing aid, which hearing aid copied the claims herein. Interton also lauded the revolutionary nature of the open ear hearing aid.

The declaration also informed the Office that Oticon's Delta hearing aid was selected as an International CES Best of Innovations 2007 Design and Engineering awards winner. Oticon was taughted as having a "revolutionary" product in the Delta, indicating that the industry clearly considered the configuration as new and innovative.

D. THE FOURTH DECLARATION OF LEON HIRSCH

On March 15, 2007, we submitted a fourth Declaration from Leon Hirsch, which declaration detailed how a fifth large competitor, Phonak, introduced the microSavia Art CRT ("Canal Receiver Technology") hearing aid, which hearing aid copied the claims herein. The Declaration provided additional evidence that Vivatone's configuration is being copied over and over again by Vivatone's major competitors.

E. THE DECLARATIONS OF DRS. BERLIN AND GLASER

On March 15, 2007, we submitted the declarations of Drs. Berlin and Glaser to provide the Examiner and the record with the analyses and opinions of those skilled in the art concerning both the technical and interpretive aspects of the merit-based claims as well as their insight into the viability of the evidence of secondary considerations.

Their testimony confirms that the prima facie case fails. Their testimony also overwhelmingly validates and bolsters the viability of the secondary consideration evidence.

The Applicants have made diligent efforts, both here and in the previous record, to illustrate how the Examiner's prima facie case of obviousness is fatally flawed. The Applicants have also provided tremendous evidence of secondary consideration in support of patentability by way of the three consecutive Declarations of Leon Hirsch, and the subsequent Declarations of Drs. Berlin and Glaser. The claims should be judged patentable on either or both accounts.

CLAIMS APPENDIX

1. A hearing aid, comprising:

a microphone sampling position located externally of an ear canal of a user;

a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;

wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit;

the receiver generating about three decibels or below of insertion loss over a portion of the human ear audible frequencies.

2. The hearing aid according to claim 1, wherein the receiver generates about two decibels or below of insertion loss over a portion of the human ear audible frequencies.

3. The hearing aid according to claim 2, wherein the receiver generates about one decibels or below of insertion loss over a portion of the human ear audible frequencies.

4. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 2200 Hertz and about 5300 Hertz.

5. The hearing aid according to claim 4, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3000 Hertz and about 5000 Hertz.

6. The hearing aid according to claim 5, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3500 Hertz and about 4500 Hertz.

7. The hearing aid according to claim 1, wherein the receiver is positioned within the bony and/or cartilaginous region of the ear canal of the user.

8. The hearing aid according to claim 1, wherein the receiver has a maximum lateral dimension that is less than half a maximum lateral dimension of a user's ear canal.

9. The hearing aid according to claim 8, wherein the receiver has a maximum lateral dimension that is less than thirty percent of half a maximum lateral dimension of a user's ear canal.

10. The hearing aid according to claim 9, wherein the receiver has a maximum lateral dimension that is less than twenty percent of half a maximum lateral dimension of a user's ear canal.

11. The hearing aid according to claim 10, wherein the receiver has a maximum lateral dimension that is less than ten percent of half a maximum lateral dimension of a user's ear canal.

12. The hearing aid according to claim 11, wherein the receiver has a maximum lateral dimension that is less than five percent of half a maximum lateral of a user's ear canal.

19. The hearing aid according to claim 1, wherein the electrical connection comprises an intermediate connecting portion, wherein a retaining member extends from at least one of the intermediate connecting portion and the receiver, and further wherein the retaining member is configured to engage at least a portion of the concha of a user's ear.

21. The hearing aid according to claim 19, wherein the retaining member is configured such that the receiver has a maximum insertion depth into an ear canal.

22. The hearing aid according to claim 19, wherein the retaining member is configured such that the receiver does not substantially contact any portion of an ear canal when inserted within the ear canal.

23. The hearing aid according to claim19, wherein the retaining member stabilizes the receiver in the ear canal.

24. The hearing aid according the claim 19, wherein the retaining member prevents movement of the receiver in the ear canal.

26. The hearing aid according to claim 1, wherein the speaker is at least partially enclosed within a casing having first and second end portions, the first end portion communicating with an intermediate connecting portion, the speaker communicating with a port provided at the second end portion of the casing.

27. The hearing aid according to claim 26, wherein the port is at least partially sealed to debris by a membrane or mesh material.

28. The hearing aid according to claim 27, wherein the casing is sealed to debris at the first end portion and along a length of the casing extending from the first end portion to the port.

29. The hearing aid according to claim 26, wherein the port includes a removable cerumen collector.

35. The hearing aid according to claim 1, wherein the electrical connection comprises an intermediate connecting portion including at least two electrical conducting components provided within the intermediate connecting portion, wherein the at least two electrical conducting components are provided within at least two channels at least partially isolated from one another.

36. A hearing aid, comprising:

a microphone sampling position located externally of an ear canal of a user;
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit;
the receiver having a maximum lateral dimension that is less than fifty percent of the maximum lateral dimension of a user's ear canal.

37. The hearing aid according to claim 36, wherein the receiver has a maximum lateral dimension that is less than forty percent of the maximum lateral dimension of a user's ear canal.

38. The hearing aid according to claim 36, wherein the receiver has a maximum lateral dimension that is less than thirty percent of the maximum lateral dimension of a user's ear canal.

40. The hearing aid according to claim 1, comprising:
wherein the electrical connection comprises an intermediate connecting portion,
an electrical conducting component and a stiffening member, provided on or in at least a portion of the intermediate connecting portion.

42. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1000 Hertz and about 2500 Hertz.

43. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1500 Hertz and about 2500 Hertz.

44. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1500 Hertz and about 2000 Hertz.

45. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1500 Hertz and about 1800 Hertz.

46. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 2000 Hertz and about 3500 Hertz.

47. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 2500 Hertz and about 3000 Hertz.

48. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3000 Hertz and about 4000 Hertz.

49. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3000 Hertz and about 3500 Hertz.

50. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3500 Hertz and about 4000 Hertz.

51. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3500 Hertz and about 5000

Hertz.

52. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 4000 Hertz and about 4500 Hertz.

53. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 4500 Hertz and about 5000 Hertz.

54. The hearing aid according to claim 1, wherein the receiver is positioned within the cartilaginous region of the ear canal of the user.

55. The hearing aid according to claim 1, wherein the receiver is suspended within and away from the walls of the ear canal.

56. The hearing aid according to claim 36, wherein the receiver is positioned within the cartilaginous region of the ear canal of the user.

57. The hearing aid according to claim 36, wherein the receiver is suspended within and away from the walls of the ear canal.

58. The hearing aid according to claim 19, wherein the retaining member is a wire.

59. The hearing aid according to claim 40, wherein the stiffening member is a wire.

60. The hearing aid according to claim 1, wherein the hearing loss programming is saved in memory provided in the behind the ear unit.

61. The hearing aid according to claim 36, wherein the hearing loss programming is saved in memory provided in the behind the ear unit.

62. The hearing aid according to claim 1, wherein the hearing loss programming is reprogrammable.

63. The hearing aid according to claim 36, wherein the hearing loss programming is reprogrammable.

64. The hearing aid according to claim 1, wherein a plurality of hearing loss programs are provided in the behind the ear unit.

65. The hearing aid according to claim 36, wherein a plurality of hearing loss programs are provided in the behind the ear unit.

66. The hearing aid according to claim 64, wherein said plurality of hearing loss programs are selectable by the user.

67. The hearing aid according to claim 65, wherein said plurality of hearing loss programs are selectable by the user.

EVIDENCE APPENDIX

Copies of the following declarations are attached hereto, including the following Declarations:

A. THE FIRST DECLARATION OF LEON HIRSCH, submitted September 14, 2006.

B. THE SECOND DECLARATION OF LEON HIRSCH, submitted November 2, 2006.

C. THE THIRD DECLARATION OF LEON HIRSCH, submitted November 28, 2006.

D. THE FOURTH DECLARATION OF LEON HIRSCH, submitted March 15, 2007.

E. THE DECLARATION OF DR. BERLIN, submitted March 15, 2007.

F. THE DECLARATION OF DR. GLASER, submitted March 15, 2007.

G. THE DECLARATION OF DR. BAUMAN, submitted March 15, 2007.

RELATED PROCEEDINGS APPENDIX

No opinions have been issued in related application serial number 10/325,529.

CONCLUSION

In view of the foregoing, it is urged that the final rejection of Claims 1-12, 19, 21-24, 26-29, 35-38, 40 and 42-67 be overturned. The final rejection is in error and should be reversed. The fee set forth in 37 CFR 41.20(b)(2) is enclosed herewith. If there are any additional charges with respect to this Appeal Brief, or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

CANTOR COLBURN, LLP

By: /H. M. Bedingfield/

H.M. Bedingfield
Registration No. 44,530
55 Griffin Road South
Bloomfield, CT 06002
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No. 23413

Date: February 19, 2008